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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,979	AI-LAMEE ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 22* is/are pending in the application.

4a) Of the above claim(s) *10-20 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/10/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I and the species where Formula I is poly(vinylbutyral-co-vinylalcohol-co-vinylacetate) with a Mw from 50,000 to 80,000, and 88% vinylbutyral groups and Formula II is poly(vinylpyrrolidone-co-vinylacetate) with an average Mw of 50,000 in the reply filed on May 5, 2008 is acknowledged. The traversal is on the grounds that 1) no unity of invention was indicated during PCT prosecution, 2) the combination of references cited is irrelevant to the claims, 3) the inventions will have unity, and 4) the recited Markush group has only two members and would not be a serious burden to search. This is not found persuasive as detailed below

1) The USPTO is not bound by the findings of the international search authority/PCT Examiner regarding the unity of invention or lack thereof. Thus their lack of indication of lack of unity does not preclude the current Examiner from raising the issue.

2) Applicant has claimed two polymers in a composition in claim 1. The Formula 1 polymer can be a homopolymer (x = y = 0), a binary block copolymer (z = 0), or a ternary block copolymer while Formula 2 can be a homopolymer (m = 0) or a binary block copolymer. Thus the embodiment does exist that is common to all the inventions where a ternary polymer is present with a homopolymer. Ding et al. in view of Eder et al. teach this embodiment along with particular monomers claimed by applicant. This teaching means the common technical feature is not special and the inventions/species lack unity.

3) Applicant has cited that the restriction requirement is contrary to rule 37 CFR 1.475(b). This recitation neglects that of 37 CFR 1.475 (a) which states, "Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only

when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. "Applicant has not fulfilled the requirement of this portion of the rule, in that there is no special technical feature shared by all the inventions that contributes over the prior art.

4) Applicant suggests that there are only two species recited in the Markush group of claim 1 and that this small group necessitates that the breadth of the claimed genus be searched. In fact when all the options of configurations of Formula 1 and Formula 2 are consider, there are six, not two, sub-genus groupings recited by claim 1. Claim 5 further expounds upon a portion of the breadth Formula 1 where the A and C monomers can each be independently substituted with a hydrogen, any alkyl, any alkenyl, any alkynyl, or any aryl group. The number of options this creates when factored into each of the six sub-genus groupings itself illustrates the breadth of the claims and the burden to have to search them in their entirety. Applicant has stated that "there are only two different ingredients recited in claim 1." If this is anadmission that the population of polymers recited by Formula 1 are equivalent and therefore obvious over one another as well as that the population of polymers recited by Formula 2 are equivalent and therefore obvious over one another, then the Examiner would be willing to consider rejoining these species. Absent this admission, the species are considered to present an undue burden to search and lack unity as stipulated by PCT Rule 13.1 and 13.2.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 6, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "from about X to Y" in claims 3 and 6 as well as "from about X to about Y" in claim 7 are relative phrases, which render the claims indefinite. The phrases "from about X to Y" and "from about X to about Y" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The phrase "from X to Y" typically indicates a minimum and maximum point. However, the phrase "from X to Y" is controverted by the term "about" which implies that values above and below both X and Y are permitted. Further, the extent of variance permitted by "about" is unclear in the context. Therefore it is unclear whether "about X" simply includes a small deviation (e.g. 10%-20%) or if a larger deviation (e.g. 25%-100%) is included as well. A similar amount of deviation is possible for Y. Thus the interpretation of the phrases "from about X to Y" and "from about X to about Y" in this context is unclear as no definitive upper and lower bound can be defined.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding (U.S. Patent No. 7,294,3290 in view of Hsu et al. (U.S. Patent No. 6,340,465) and the Technical Information on Kollidon VA 64 reference (2000).

Ding teaches a drug-containing poly(acetal) based coating for an implantable medical device, where stents are exemplified as envisioned devices (see abstract and column 5 lines 22-30). In particular, Ding teaches a terpolymer of vinyl butyral, vinyl alcohol and vinyl acetate envisioned in the coating composition (see claim 2, column 3 lines 21-27; instant claims 1 and 5). Variants of this polymer have the vinyl butyral constituting about 88% of the polymer

backbone, with about 11% vinyl alcohol and the balance vinyl acetate (see column 3 lines 52-54; instant claims 6 and 7). The molecular weight (M_w) of this polymer is taught to be between 40,000 and 250,000 (see column 3 lines 31-32; instant claim 7). "In the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed.Cir. 1990)" (see MPEP 2144.05). Here the taught molecular weight range contains the elected range of 50,000 to 80,000 and thereby makes it obvious (see instant claim 7). Ding goes on to teach particularly envisioned drugs to include within the coating composition and these include both rapamycin and dexamethasone, as well as compounds that inhibit restenosis (see claims 2-3, column 5 lines 51-55, and column 6 lines 26-27 and 32; instant claim 8). An example demonstrates that Ding et al. contemplated the drug to be present in the coating at about 1:2 drug to vehicle (polymer) (see example 5; instant claim 9). Further, Ding teaches that the polymers may be blended with other polymers that include vinyl acetate, but does not specifically teach a copolymer of vinyl pyrrolidone and vinyl acetate (see claim 10, column 4 lines 48-51, and column 5 line 14; instant claim 1).

Hsu et al. teach a coating composition for implantable medical devices that confers lubricity to the device surface (see abstract and column 1 lines 10-11). Hsu et al. go on to teach the inclusion of a polyvinylpyrrolidone-vinyl acetate copolymer in the coating to enhance the lubricity to the coating (see column 3 lines 56-60 and column 9 lines 31-35; instant claim 1). Such a lubricity enhancing compound is exemplified in the coating composition at 0.4% and 0.5% (including solvent) or 43% and 49% (without solvent) (see table 1 one step solution and example 3 solution B; instant claim 2). Since the implantation of a device would be facilitated by it having a lubricious outer surface (e.g. easier and faster implantation), it would have been obvious to one of ordinary skill in the art at the time the invention was made to select a

polyvinylpyrrolidone-vinyl acetate copolymer as a particular "other polymer" to use in the invention of Ding and employ it at the taught percentages. Further since polyvinylpyrrolidone-vinyl acetate copolymers were known to be used in coatings of implantable medical devices at the time of the invention, one of ordinary skill in the art would have had a reasonable expectation of success for its use in the composition of Ding. Ding in view of Hsu et al. does not teach the molecular weight of the polyvinylpyrrolidone-vinyl acetate copolymer or the proportion of monomers present in the polymer.

The Technical Information on Kollidon VA 64 reference teaches a polyvinylpyrrolidone-vinyl acetate copolymer known for use in drug delivery and film forming applications (see page 1 section 1.1, page 7 section 3.1, and page 8 section 3.3). The polymer is taught to have 60% vinylpyrrolidone and 40% vinyl acetate (see page 4 section 1.2; instant claim 3). Further, the molecular weight (M_w) it taught to be between 45,000 and 70,000 (see page 6 section 2.10). The reference does not specifically teach the molecular weight to be 50,000. However, this molecular weight it within the taught range and at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such a parameter as a matter of routine experimentation. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a polyvinylpyrrolidone-vinyl acetate copolymer with a 60:40 ratio of vinylpyrrolidone to vinyl acetate and a molecular weight of 50,000 in the invention of Ding in view of Hsu et a. Therefore claims 1-9 are obvious over Ding in view of Hsu et al. and the Technical Information on Kollidon VA 64 reference.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding in view of Hsu et al. and the Technical Information on Kollidon VA 64 reference as applied to claims 1-8 above, and further in view of Sass (U.S. Patent No. 6,383,215).

Ding in view of Hsu et al. and the Technical Information on Kollidon VA 64 reference make obvious a coating composition with poly(vinylburtyral-co-vinylalcohol-co-vinylacetate) with a M_w from 50,000 to 80,000, and 88% vinylbutyral groups, poly(vinylpyrrolidone-co-vinylacetate) with an average M_w of 50,000, and a bioactive. This modified reference does not teach the inclusion of 17β-estradiol.

Sass teaches that 17β-estradiol is known to inhibit smooth muscle cell growth and is used to inhibit restenosis and in-stent stenosis (see column 2 lines 50-57; instant claim 8). Since Ding teaches the inclusion of compounds that inhibit restenosis in the coating composition, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ 17β-estradiol in the coating composition of Ding in view of Hsu et al. and the Technical Information on Kollidon VA 64 reference. Therefore claims 1-8 are obvious over Ding in view of Hsu et al., the Technical Information on Kollidon VA 64 reference, and Sass.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/MP WOODWARD/
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